UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

INNOGENETICS N.V.,
a Belgian Corporation,

Plaintiff,

v.

Case No. 05-C-0575-C

ABBOTT LABORATORIES,
an Illinois Corporation,

Defendant.

BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT

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INTRODUCTION

On November 12, 1997, following a lengthy examination in the United States Patent and Trademark Office ("USPTO") and as part of the notice of allowability of the claims of what became United States Patent 5,846,704 ("the '704 patent"), the patent examiner articulated her reasons for allowance, *inter alia*, as follows:

> ***The claims are allowable over the prior art because the instant methods are concerned with "genotyping" HCV rather than just "detecting" HCV.*** Although genotyping falls under the umbrella of detecting, it is a specific and selective type of detection whereby different genotypes of similar virus strains can be distinguished. Mere detection methods permit detection of numerous types and subtypes of HCV without distinguishing among them. Hence, the term "method of genotyping" means distinguishing among HCV types and/or subtypes. The prior art recognizes the problem of genotyping HCV versus detecting HCV and others have developed methods of genotyping by exploiting sequences that are non-conserved among HCV types. The most divergent sequences have turned out to be in coding regions of the HCV genome. Okamoto et al. (1992) J. Gen Virol. use the "C" gene as [the] basis for distinguishing genotypes. ***The instant inventors have gone against conventional wisdom and used the 5'-untranslated region to make probes for genotyping. The 5'-UTR has not been used before for genotyping because it is so highly conserved among isolates.*** Applicant, however, has found specific regions, that apparently belong to a stem loop structure, in the 5'-UTR that exhibit enough heterogeneity among isolates to be exploited for genotyping. ***Although the sequences of several 5'-UTR are known in the art, and genotyping methods are known in the art, it is not suggested or motivated to use the 5'-UTR for genotyping. Indeed, the ordinary artisan would be motivated to avoid the 5'-UTR for genotyping because of its high sequence conservation.*** Moreover, Cha et al. (1991) use the 5'-UTR to design "universal probes" for general HCV detection just because the 5'-UTR is so highly conserved.

PPFF 71 (emphasis added). In coming to these conclusions, the USPTO had in front of it all relevant prior art that bore on its determinative distinction between "genotyping" and "detecting."

Undeterred by the facts or the law, defendant Abbott Laboratories ("Abbott") has accused plaintiff Innogenetics N.V. ("Innogenetics") of committing inequitable conduct, primarily on the basis of its contention that, in contrast to the prosecution of a related European application, Innogenetics did not expressly argue or attempt to distinguish one of several references by Tai-An Cha *et al.*, a 1992 Patent Cooperation Treaty ("PCT") application, Serial No. WO 92/19743 (the "Cha PCT application"). Even a cursory review of the '704 prosecution history should have precluded such a charge; Innogenetics disclosed the Cha PCT application to the USPTO and that application appears *not once, but twice* in the prosecution history of the '704 patent. PPFF 13, 16, 22.

Furthermore, as made explicit in writings of Cha *et al.* which were contemporaneous with the Cha PCT application, the Cha group did not disclose the invention claimed in the '704 patent. The '704 patent discloses a method of genotyping that could be used instead of the prior, laborious process of sequencing long stretches of DNA in the hepatitis C virus ("HCV") genome. PPFF 119. Specifically, the '704 patent discloses a rapid method of genotyping in which oligonucleotide probes are specifically hybridized to target regions in the 5-prime untranslated region ("5' UTR" or "5UT region") of HCV. PPFF 73. In contrast, in a 1992 article from the prestigious journal, *Proceedings of the National Academy of Sciences* ("PNAS"), entitled "At least five related, but distinct, hepatitis C viral genotypes exist" ("the 1992 Cha article"), communicated to PNAS contemporaneously with the filing of the Cha PCT application, Cha *et al.* concluded that it was "imperative to" continue sequencing long stretches of DNA in multiple regions of the HCV genome in order to determine genotype:

> [i]t is ***imperative*** to examine longer segments of sequence for each isolate *in several domains* to discern different genotypes. For instance, isolates US4 and US5 ***cannot be assigned to different genotypes based on the 5UT region alone*** (Fig. 2A) unless other domains (Fig. 2B and C) are taken into consideration.
>
> * * *
>
> When only the 5UT region is considered, fewer distinct genotypes can be assigned. On the other hand, when only the hypervariable region is considered, each isolate will represent a unique genotype. ***We should emphasize that long segments of sequence in several domains should be examined together for each isolate to classify its genotype.***

PPFF 39, 43 (emphasis added).[1]

In addition, Abbott's charge takes no account of the differences between the claims Innogenetics prosecuted in the United States and those it prosecuted in Europe, and further relies on the unsupported assumption that the relevant law governing those distinct prosecutions is the same, an assumption criticized by numerous authorities.

Finally, not only did the inventors of the '704 patent disclose the Cha PCT application to the USPTO, a U.S. patent application based on that same Cha PCT application was being examined by the same supervisory examiner handling the '704 patent examination, at the same time as the '704 patent application. PPFF 109. Given the interference issues raised by the simultaneous prosecution in the USPTO of both the '704 patent and the U.S. application corresponding to the Cha PCT application, Innogenetics believes that the Court can be assisted by the analysis of attorney Michael

[1] The 1992 Cha *et al.* article was communicated to the journal nine days before the Cha PCT application was filed. PPFF 41. The Cha PCT named five inventors, each of whom are among the six authors of the 1992 Cha article. PPFF 42.

Sofocleous as set forth in his May 2, 2006 expert report (dkt. 43). Although Mr. Sofocleous is presently in private practice, he was formerly an employee of the USPTO for over thirty years, including 23 years as a patent interference examiner, Examiner-in-Chief and Administrative Patent Judge overseeing patent interferences. PPFF 121. As explained more fully below, if Abbott's theory with respect to the Cha PCT application were correct, the supervisory examiner overseeing both applications would have been duty bound to declare an interference between the '704 patent (or application for the '704 patent) and the Cha U.S. application.

It is Innogenetics' contention in this motion that Abbott did not conduct the factual or legal analysis necessary to bring the serious charge of inequitable conduct. As a result, Abbott's assertion of inequitable conduct in its answer, affirmative defenses and counterclaims (dkt. 7-8), not to mention its persistence in maintaining this charge even after it took significant discovery on the topic, has caused Innogenetics to incur substantial and unnecessary costs in pursuing its patent case.[2] Accordingly, Innogenetics asks the Court not only to grant its motion for summary judgment of no inequitable conduct, but to award it its full costs and reasonable attorneys fees in defending against this charge and in prosecuting this motion.

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[2] By way of example, Innogenetics has had to pay for the depositions of its U.S. patent counsel, Charles Muserlian, two European patent attorneys, Catherine Grosset-Fournier and Ann De Clercq, a former Innogenetics patent counsel, Dr. Philippe Jacobs, and has had to take the deposition of Abbott's European patent "expert," Devanand Crease, and retain its own U.S. patent prosecution expert, Michael Sofocleous.

STATEMENT OF UNDISPUTED FACTS

On July 18, 1994, four inventors, Dr. Geert Maertens, Dr. Lieven Stuyver, Dr. Rudi Rossau, and Dr. Hugo Van Heuverswyn ("Applicants" or "Maertens *et al.*") filed U.S. Patent Application, Serial No. 08/256,568 entitled "Process for Typing HCV Isolates" ("the '568 application"), in the USPTO. PPFF 5, 6. The '568 application disclosed and claimed a method of genotyping isolates of the hepatitis C virus using probes that specifically hybridize to target sequences in the 5' UTR of HCV. PPFF 7. As filed, the '568 application contained 23 claims. PPFF 8.

The '568 application was the U.S. national stage of international patent application ("PCT") No. EP93/03325 ("Maertens PCT application"), which was filed on November 26, 1993.[3] PPFF 10. The Maertens PCT application claims priority to European Patent Office ("EPO") Application No. 93,402,129.6, filed on August 31, 1993, and EPO 92,403,222.0, filed on November 27, 1992. PPFF 12.

I. THE '568 APPLICATION WAS SUBMITTED TO THE USPTO ALONG WITH, *INTER ALIA*, A PRIOR ART STATEMENT, AN INTERNATIONAL SEARCH REPORT, AND COPIES OF THE CITED REFERENCES.

Mr. Charles Muserlian, a United States patent attorney, prosecuted the '568 application before the USPTO on behalf of Maertens *et al.* PPFF 9. Upon filing the '568 application on July 18, 1994, Mr. Muserlian also filed the International Search Report

[3] The Maertens PCT application was published as WO 94/12670 on June 9, 1994. PPFF 11.

("ISR")[4] that was issued by the International Searching Authority on June 2, 1994. PPFF 13, 14. When submitting the '568 application and the ISR, Mr. Muserlian also submitted (i) copies of the eight references cited in the ISR, (ii) a prior art statement, (iii) a corresponding European search report, and (iv) a form referred to as PTO Form 1449, which listed each of the same references. PPFF 13. The USPTO acknowledged receipt of these papers and the copies of the references cited in the ISR. PPFF 15.

One of the references cited in the ISR was PCT Application WO 92/19743, filed by Cha *et al.* entitled "HCV Genomic Sequences for Diagnostics and Therapeutics," which was published on November 12, 1992 ("the Cha PCT application"). PPFF 16. The ISR designates the Cha PCT application both as an "X" document ("the claimed invention cannot be considered novel or cannot be considered to involve an inventive step") and an "A" document ("document defining the general state of the art which is not considered to be of particular relevance"). PPFF 17. The seven other prior art references were also noted on the ISR as being "A" documents. PPFF 21.

Two copies of the Cha PCT application can be found in the certified copy of the '568 application's prosecution history. PPFF 22. The first page of the first copy of the Cha PCT application that appears in the certified prosecution history bears a date stamp, "18 JUL 1994," which is the date that the '568 application was filed with the USPTO.

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[4] An ISR is a document which discloses the results of the independent prior art search from the designated International Searching Authority, which, in this case, was the European Patent Office. Manual of Patent Examining Procedure Appx. T, Patent Cooperation Treaty, Article 15 (available at http://www.uspto.gov/web/offices/pac/mpep/documents/appxt_a15.htm#pctarticle-15). The ISR is also referred to by its form name, Form PCT/ISA/210. PPFF 13.

PPFF 5, 23. Additionally, page 1 of the ISR contains a written check mark next to "WO, 92, A, 19743" (the Cha PCT application). PPFF 24. This check mark denotes at a minimum receipt of the document by the USPTO and suggests review by the examiner. PPFF 25.

One of the other documents submitted by Mr. Muserlian was a letter containing a prior art statement. PPFF 13. The statement notes that the references listed in the ISR were being provided to the USPTO and reads in full as follows:

> In order to comply with the requirements of Rule 56, Applicants are submitting herewith copies of the references cited in the search report in the French application corresponding to the above application as well as PTO form 1449. A copy of the search report was submitted with the application as filed. It is deemed that the references do not relate to the invention and, therefore, further discussion of the same is not necessary.

PPFF 26. Mr. Muserlian's statement that the references "do not relate to the invention" was standard form language he used in such circumstances. PPFF 81. Ten days later, on July 28, 1994, Mr. Muserlian filed a "Note Transmittal," informing the USPTO that his original prior art statement stated incorrectly that the search report came from the French application and explained that the search report was actually from the European application. PPFF 27. The July 28, 1994 letter clarified as follows:

> In reviewing the above application, it was noted that the Search Report being submitted with the application issued in the French patent corresponding to the application as can be easily seen from the documents submitted with the Prior Art Statement it was a Search Report issued in the corresponding European Application. The error is regretted.

PPFF 28. This letter also included copies of the PTO Form 1449 and the July 18, 1994

prior art statement. PPFF 29.

The USPTO acknowledged receipt of all the papers described above. PPFF 15, 30. Also, on October 19, 1994, Rita D. Smoot, a Legal Document Review Clerk, reviewed the filed documents, indicating, *inter alia*, receipt of PCT/ISA/210-Search Report (*i.e.*, the ISR, *see* fn. 4, *supra*) and the references cited therein. PPFF 31. On October 21, 1994, the USPTO mailed a notification of acceptance of application. PPFF 33. The notification acknowledged receipt, *inter alia*, of the following documents: a preliminary amendment, filed July 18, 1994; the information disclosure statement, filed July 18, 1994; a copy of the search report; and copies of the references cited therein. PPFF 34.

II. THE PROSECUTION AND EXAMINATION OF THE '568 APPLICATION.

Examiner Amy Atzel, Ph.D., was the assistant examiner for the '568 application. PPFF 35. Examiner W. Gary Jones supervised Examiner Atzel on the '568 application. PPFF 36. Examiner Atzel, conducted her own search of the prior art and attached the results of her search to a PTO Form-892. PPFF 37, 38. PTO Form-892 is a Notice of References Cited. PPFF 38. The PTO Form-892 lists, *inter alia*, the 1992 Cha article. PPFF 40.

A preliminary amendment to the '568 application was submitted on July 18, 1994. PPFF 44. The purpose of the preliminary amendment was to conform the claims set forth in the Maertens PCT application with U.S. patent office procedures. PPFF 45.

In an office action dated April 8, 1996, examiner Atzel issued a "restriction requirement," stating that the claims are directed to three patentably distinct inventions, *i.e.*, Group I (Claims 1-5 and 8-18) drawn to processes for genotyping HCV; Group II (Claims 6 and 7) drawn to DNA or RNA probes; and Group III (Claims 19-23) drawn to a kit and solid supports for *in vitro* discrimination of HCV isolates. PPFF 46. Examiner Atzel required the prosecution of the '568 Application to be restricted to one of Groups I to III. PPFF 47. On May 2, 1996, Maertens *et al.* filed a response to the office action informing the examiner that they elected the claims of Group I. PPFF 48.

On July 12, 1996, examiner Atzel mailed a second office action. PPFF49. In the second office action, examiner Atzel acknowledged, *inter alia*, the election of Group I, and also rejected the claims of Group I, *inter alia*, as obvious pursuant to 35 U.S.C. § 103 over several prior art references. PPFF 50, 51. Three of these references – Bukh *et al.*, Okamoto *et al.* (J. Gen. Virol.) and Lee *et al.* – were among those cited in the ISR that was submitted by Mr. Muserlian with the '568 application. *See* PPFF 52. Examiner Atzel also cited in her rejections the 1992 Cha article, as well as a November 1991 Cha article, J. Clin. Microbiol. 29:2528-34 (the "1991 Cha article"). PPFF 53.

On January 13, 1997, Maertens *et al.* filed an amendment in response to the second office action. PPFF 54. In the amendment, Maertens *et al.* canceled all the pending claims and added new claims 24 to 39. PPFF 55. Additionally, in response to the examiner's rejections under 35 U.S.C. §§ 102 and 103, the applicants made several

arguments explaining why the invention claimed in the '568 application was unique and distinguishable from the prior art.[5] PPFF 56.

On April 18, 1997, examiner Atzel, after updating her search of the prior art, mailed a final office action. PPFF 57, 58. In the final office action, she rejected the pending claims as unpatentable under 35 U.S.C. §§ 102 and 103 over several prior art references including the 1991 and 1992 Cha articles. PPFF 59. At page 3 of the action, examiner Atzel stated:

> * * * The method of claim 24 is sufficiently broad that it reads on any method involving a "probe" or "primer" that is ***capable of hybridizing*** to the 5'-UTR. Claim 24 is not limited to ***probes that specifically hybridize*** to the positions –291 to –66 of the 5'-UTR, but only **to *probes capable of doing so . . . .***

PPFF 60 (emphasis added). Hence, examiner Atzel drew a distinction between the then-claimed phrase "capable of hybridizing" which could broadly sweep in probes that were merely capable of hybridizing in the 5' UTR, and the narrower phrase "specifically hybridizes" which would require the actual specific hybridization of the probes in the 5' UTR. The final office action was also reviewed and signed by her supervisor, W. Gary Jones. PPFF 61.

On October 2, 1997, Dr. Maertens, Mr. Muserlian and Dr. Philippe Jacobs, a representative from Innogenetics' patent department, attended an interview with

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[5] Abbott selects five phrases from the eleven pages of remarks submitted in the January 13, 1997 Amendment in support of its contention that Innogenetics made "numerous false and/or misleading representations and omissions to the P.T.O. . . . regarding the prior art generally or the Cha Application in particular[.]" *See* Abbott's Answer to Interrogatory No. 1, at 4 (attached as Ex. 5 to the Declaration of Melody K. Glazer ("Glazer Decl.")). Abbott's contentions are addressed in the Argument, Section II, *infra*.

examiner Atzel to discuss the '568 application. PPFF 62.[6] The Interview Summary Record states that all pending claims were discussed as well as the "Cha" and "Okamoto" references. PPFF 63. The summary describes the general nature of what was discussed as follows:

> [Applicant] explained that using UTR for genoytyping is not motivated by prior art because UTR is highly conserved. [The prior] Art says best probes are in "coding regions." UTR probes have been used for "detecting HCV" in general but not "typing". Discussed extensive revisions to claims that more clearly define invention.

PPFF 64.

On October 20, 1997, Maertens *et al.* filed a Rule 116 Amendment in response to the final office action dated April 18, 1997. PPFF 65. In the Rule 116 Amendment, Maertens *et al.* canceled claims 24-39 and added claims 40-52. PPFF 66. Applicants also submitted their response to the examiner's reasons for rejection set forth in the final office action. PPFF 67. Notably, in response to the final rejection and in accordance with the examiner's suggestion, applicants amended the claims to replace the phrase using a probe "capable of hybridizing" with the phrase "using a probe that specifically hybridizes." PPFF 68.

On November 12, 1997, examiner Atzel mailed a Notice of Allowability and an Examiner's Amendment. PPFF 69. By this time, the examiner had updated her prior art

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[6] Abbott also contends that Innogenetics made "numerous false and/or misleading representations and omissions to the P.T.O. ... regarding the prior art generally or the Cha Application in particular" during the interview with the Examiner, although Abbott cites no specific statements – or anything else, for that matter – to support this allegation. *See* Abbott's Answer to Interrogatory No. 1, at 4 (Glazer Decl. Ex. 5).

search *and had conducted an interference search.* PPFF 70. The examiner stated her reasons for allowing the claims over the prior art in part as follows:

> The claims are allowable over the prior art because the instant methods are concerned with "genotyping" HCV rather than just "detecting" HCV.
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> * * *
>
> The instant inventors have gone against conventional wisdom and used the 5'-untranslated region to make probes for genotyping. The 5'-UTR has not been used before for genotyping because it is so highly conserved among isolates.
>
> * * *
>
> Although the sequences of several HCV 5'-UTR are known in the art, and genotyping methods are known in the art, it is not suggested or motivated to use the 5'-UTR for genotyping. Indeed, the ordinary artisan would be motivated to avoid the 5'-UTR for genotyping because of its high sequence conservation.

PPFF 71. The notice of allowance was drafted by examiner Atzel and was reviewed and signed by her supervisor, W. Gary Jones. PPFF 72. On December 8, 1998, the claims of the '568 application issued as U.S. Patent No. 5,846,704. PPFF 73.

ARGUMENT

To succeed on a motion for summary judgment, the moving party must show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). When the moving party succeeds in showing the absence of a genuine issue as to any material fact, the opposing party must set forth specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e); *Matsushita Elec. Indus. Co. v. Zenith Radio*

Corp., 475 U.S. 574, 586 (1986). If a party fails to make a showing sufficient to establish the existence of an essential element on which that party will bear the burden of proof at trial, summary judgment for the opposing party is proper. *Celotex*, 477 U.S. at 322.

These principles apply equally in the context of a claim of inequitable conduct; that is, summary judgment of no inequitable conduct is appropriate where "drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant can not prevail." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir. 1998) (affirming grant of summary judgment of no inequitable conduct).

I. TO PROVE INEQUITABLE CONDUCT, ABBOTT MUST PROVE BY CLEAR AND CONVINCING EVIDENCE BOTH THAT INNOGENETICS MADE MATERIALLY FALSE STATEMENTS AND THAT THESE FALSE STATEMENTS WERE MADE WITH AN INTENT TO DECEIVE THE USPTO.

It has been oft repeated that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague." *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The Federal Circuit, in an attempt to mitigate this "plague," has reaffirmed that "[i]nequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to deceive, and those two elements, materiality and intent, must be proven by clear and convincing evidence." *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988). As the Federal Circuit recently reiterated:

> A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution. The party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence.

> Further, materiality does not presume intent, which is a separate and essential component of inequitable conduct.

Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 1001 (Fed. Cir. 2006) (internal quotation marks and citations omitted).[7]

In considering the materiality prong of this test, courts routinely look to the definition provided in 37 C.F.R. § 1.56 (relating to the patent applicant's duty of disclosure to the USPTO):

> [I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
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> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
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> (2) It refutes, or is inconsistent with, a position the applicant takes in:
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> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b). The Federal Circuit has held that "determining whether there was intent to deceive is still a contextual exercise, and 'materiality does not presume intent, which is a separate and essential component of inequitable conduct.'" *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1346 (Fed. Cir. 2005) (quoting *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001)). While intent may be inferred from the circumstances surrounding the applicant's conduct, the Federal Circuit has held

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[7] *See also Old Town Canoe Co. v. Confluence Holdings Corp.*, Nos. 05-1123, 05-1148, 2006 U.S. App. LEXIS 11435, at *34 (Fed. Cir. May 9, 2006) ("[e]ven if materiality is shown, however, [defendant] points to no evidence of intent to deceive the PTO . . . 'which is a separate and essential component of inequitable conduct'") (quoting *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1351 (Fed. Cir. 2002)).

that "in order to find intent to deceive, 'the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.'" *Id.* (affirming district court's determination that patent was not unenforceable by reason of inequitable conduct) (quoting *Kingsdown*, 863 F.2d at 876).

Mere procedural irregularities in prosecution, without more, do not amount to inequitable conduct:

> Intent to deceive should be determined in light of the realities of patent practice, and not as a matter of strict liability whatever the nature of the action before the PTO. A patentee's oversights are easily magnified out of proportion by one accused of infringement. . . . Given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required.

Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990) (internal quotation marks and citations omitted). Indeed, even a finding that an applicant's conduct amounts to "gross negligence" does not justify an inference of intent to deceive the USPTO. *See Kingsdown*, 863 F.2d at 876.

II. ABBOTT'S CONTENTIONS OF INEQUITABLE CONDUCT ARE BASELESS.

Abbott's inequitable conduct charge appears[8] to be based on three theories: (1) Innogenetics defrauded the USPTO when it disclosed an international search report –

[8] The only basis that Abbott has provided for its inequitable conduct claim is found in its response to an Interrogatory from Innogenetics. *See* Abbott Laboratories' Answers to Innogenetics, N.V.'s First Set of Interrogatories, Interrogatory No. 1 at pp. 3-5 (Glazer Decl. Ex. 5). *Cf., e.g.*, Glazer Decl. Ex. 6, Crease Dep. at 169 ("Q: Now what if any portion of your report is relevant to Abbott's assertion of

(Footnote continued)

which included the Cha PCT application and several other prior art references – with a boilerplate statement advocating that the references disclosed on the search report "do not relate to the invention;" (2) Innogenetics defrauded the USPTO by making certain arguments during prosecution of the '704 patent when explaining why it believed its invention was patentable over prior art cited against its application by the USPTO examiner; and (3) because Innogenetics stated to the *European* Patent Office that the Cha PCT application represented the "closest prior art" to certain European claims, and made a "disclaimer" under European practice, Innogenetics somehow defrauded the USPTO. We address the first two allegations in section II.A., and the third in section II.B., below.

A. As A Matter Of Law, Innogenetics' Statements Concerning The Prior Art Cannot Amount To Fraud.

Regardless of whether the Cha PCT application can be deemed material under the broad definition identified in 37 C.F.R. § 1.56(b), it is undisputed that Innogenetics both disclosed and physically supplied the USPTO with a copy of that application. Thus, the question is not whether Innogenetics omitted material information – it did not. Rather, the question is whether Abbott has evidence sufficient to suggest that Innogenetics materially misrepresented the relevant art and did so with an intent to deceive the USPTO. On this score, Abbott identifies a handful of statements Innogenetics made during the prosecution of the '704 patent and labels them fraudulent misrepresentations. What Abbott deems misrepresentations are in fact simply arguments and positions taken

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inequitable conduct in the United States Patent Office? … A: I don't think my report is in itself – doesn't consider that issue, it doesn't consider that issue.").

by Innogenetics during the prosecution of the '704 patent concerning the relevance and applicability of the prior art *that was before the examiner*. Thus, the burden on Abbott is particularly high where, as here, the references upon which the inequitable conduct claim is primarily founded were disclosed to the examiner, and thus the examiner was free to reach his or her own conclusions about the prior art. *See, e.g.,* cases cited at pp. 22-23, *infra*.[9]

1. The Cha PCT Application Was Disclosed and Fully Before The Examiner, Who Had a Duty to Review and Reach Her Own Conclusions About It.[10]

Attempting to support its inequitable conduct claim, Abbott points to an opinion expressed in a cover letter authored by Innogenetics' U.S. patent attorney, Charles Muserlian, when submitting the prior art references listed in the ISR (including the Cha

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[9] In the comparable context where a party is challenging the *validity* of a patent, the burden of showing that the claims are invalid "is especially difficult when the prior art was before the PTO examiner during prosecution of the application." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990); *see also Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984) ("When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents."); *John Mezzalingua Assocs. v. Arris Int'l, Inc.*, Case No. 03-C-353-C, 2003 U.S. Dist. LEXIS 24730, at *33-34 (W.D. Wis. Nov. 14, 2003) (where prior art in question was before the examiner, "there is an increased burden on the defendant alleging invalidity").

[10] In its answer, Abbott initially supported it allegation of inequitable conduct with its apparent belief at the time that the Cha PCT application was not disclosed to the examiner during the prosecution of the '568 application. *See* Abbott's Answer, Affirmative Defenses and Counterclaim (dkt. 7-8), at 6, ¶ 11 ("The '704 patent is unenforceable due to plaintiff's inequitable conduct before the Patent and Trademark Office in . . . *intentionally omitting material information*, including without limitation, making false and misleading statements and *intentionally omitting material information* relating to [the Cha PCT application], done so with an intent to deceive the examiner.") (emphasis added). However, even the two incomplete copies of the prosecution history which Abbott's counsel brought to Mr. Muserlian's deposition on January 11, 2006, contain a copy of the Cha PCT application bearing the date stamp "18 Jul 1994." PPFF 75, 76 .

PCT application) to the USPTO. That letter stated that the references "do not relate" to the claimed invention. *See* Abbott Laboratories' Answers to Innogenetics, N.V.'s First Set of Interrogatories, at 4 (Glazer Decl. Ex. 5). Mr. Muserlian's opinion – which turned out to be correct – cannot constitute the basis of an allegation of inequitable conduct under first principles of patent examination because the examiner is deemed to have examined and come to her own opinion regarding a piece of prior art which was in front of her.

When prior art is disclosed, "[a]bsent proof to the contrary, we assume that the examiner did consider the references." *Molins PLC v. Textron*, 48 F.3d 1172, 1184 (Fed. Cir. 1995). This is because the examiner has an independent duty to examine prior art references provided by the applicant and evaluate their import, if any.

> The district court correctly noted that an examiner has a right to expect candor from counsel. Its indication that examiners "must" rely on counsel's candor would be applicable, however, ***only when the examiner does not have the involved documents or information before him***, as the examiner did here. Blind reliance on presumed candor would render examination unnecessary, and nothing in the statute or Manual of Patent Examining Procedure would justify reliance on counsel's candor as a substitute for an examiner's duty to examine the claims.

Kingsdown, 863 F.2d at 874 n.8 (emphasis added). Thus, an examiner may not blindly rely on counsel's opinions and arguments regarding prior art, and, indeed, is obligated not only to conduct her own prior art search, but to independently examine the prior art. *See N. Telecom*, 908 F.2d at 938 ("Although lapse on the part of an examiner does not exculpate an applicant whose acts are intentionally deceptive, any doubt as to whether the examiner lapsed in his duty does not increase the burden on the applicant. Nor does the

applicant's obligation of candor replace the examiner's duty to examine the claims.") (citations omitted); *Herbert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996).

Abbott seems to suggest that Mr. Muserlian's statement caused the examiner to overlook, or to give short shrift to, the Cha PCT application. But such a suggestion flies in the face of overwhelming evidence that the Cha PCT application – along with the other Cha references that were specifically discussed and distinguished – was not only before the examiner, but was reviewed and considered by the examiner in granting the patent's claims. As an initial matter, two separate copies of the Cha PCT application are in the prosecution history of the '704 patent. PPFF 22. One of them accompanied the international search report submitted by Mr. Muserlian on July 18, 1994. PPFF 13, 16. Moreover, the first page of the international search report (which reflects the European search examiner's independent prior art search, *see* fn. 4, supra) contains a written check mark next to "WO, 92, A, 19743" – the Cha PCT Application – proving, at a minimum, receipt of the reference by the USPTO. PPFF 16, 24, 25. The Federal Circuit has held that "[w]hen a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it cannot be deemed to have been withheld from the examiner." *Molins*, 48 F.3d at 1185 (internal quotation marks omitted) (applicant's failure to cite references that were otherwise of record in the application did not constitute inequitable conduct).

Moreover, strong indirect evidence supports the conclusion that the examiner did review the Cha PCT Application. In the ISR, the Cha PCT application was the only reference designated by the European search examiner as an "X" document. PPFF 18.

As explained by Mr. Sofocleous, the "X" designation on the ISR emphasizes to the U.S. examiner the need for review and consideration of the document and, as a matter of patent office practice, the U.S. examiner will review and consider such a document. PPFF 19. Further, examiner Atzel rejected claims during the prosecution of the '568 application on the basis of three references that were, like the Cha PCT application, listed on the ISR and submitted with the application – Bukh *et al.*, Okamoto *et al.* (J. Gen. Virol.), and Lee *et al.* – even though these references were not "X" documents. PPFF 18, 51, 52. If the examiner took the time to read and apply these references, a fair inference is that she did likewise with the only "X" reference. This is particularly true where, as here, the subject matter of the "X" reference was related directly to other prior articles from the same Cha group, which articles were cited expressly by the examiner.

It is undisputed on this record that Mr. Muserlian's submission of the ISR to the USPTO conformed to accepted norms relating to the filing of foreign applications in the USPTO. As Abbott's expert on European Patent Office practice and procedure testified, when there are simultaneous prosecutions related to the same invention in Europe and the United States, it is his practice to simply supply the USPTO with any international search reports and the references cited therein. PPFF 70, 78.[11] That is precisely what Mr. Muserlian did. His statement that the references in the ISR "do not relate to" the invention was standard form language he used in such circumstances. PPFF 81 ("I just

[11] *See also* PPFF 79. (Crease Dep. at 66 (the prosecuting attorney's obligation is to "disclose all prior art documents that are either relevant in your mind or that are raised during prosecution in Europe or elsewhere in the world, in the U.S.")).

say here's the prior art and it doesn't look to be relevant and, you know, if the examiner deems it relevant he cites it and then we discuss it from there. This is a standard form I would use."). Moreover, Mr. Muserlian's opinion accorded with the good faith belief held by Innogenetics that the Cha PCT application was *not* "related" to the invention disclosed in the '704 patent, PPFF 82, 83, a belief buttressed by the contemporaneous 1992 Cha article which concluded that it was "imperative" to continue sequencing long stretches of DNA in multiple regions of the HCV genome in order to determine genotype. PPFF 43. That Abbott disagrees with Innogenetics' – and the examiners' – assessment of the relevance of this reference is simply not evidence that Innogenetics intended to deceive the USPTO.

Abbott's attempt to convert Mr. Muserlian's boilerplate statement concerning the significance of prior art references that were actually disclosed to the USPTO into a case of fraud on the USPTO fails as a matter of law. *See also* cases cited in section II.A.2, *infra*.

2. Innogenetics' Arguments Distinguishing The Invention Claimed In The '704 Patent From The Prior Art Cannot Constitute Inequitable Conduct.

Abbott's contentions concerning other arguments made by Innogenetics in the USPTO fail as a matter of law for reasons similar to those already discussed. Here, Abbott strings together a series of snippets from Innogenetics' arguments to the USPTO and contends that these selective statements mischaracterized the "prior art generally" or "the Cha Application in particular." Abbott also contends that Innogenetics made "numerous false and/or misleading representations and omissions" to the USPTO, but

fails to identify any particular statements as material omissions or misrepresentations. *See* Abbott's Answer to Interrogatory No. 1, at 4 (Glazer Decl. Ex. 5). Regardless, Abbott's contentions here fail as well since advocacy regarding art before the examiner does not constitute inequitable conduct.

In *Life Technologies, Inc. v. Clonetech Laboratory, Inc.*, 224 F.3d 1320 (Fed. Cir. 2005), the applicants – who were faced with an obviousness rejection in light of a particular article – characterized the article as failing to provide a reasonable expectation of success, only later to admit that they had successfully used that very reference to achieve the teaching described therein. *Id.* at 1325-26. The Federal Circuit held that "[t]his argument [that there was no reasonable expectation of success] is simply not a misrepresentation." *Id.* at 1326. Rather, "in making the argument, the inventors merely advocated a particular interpretation of the teachings of the . . . article and the level of skill in the art, which the Examiner was free to accept or reject. This argument did not contain any factual assertions that could give rise to a finding of misrepresentation." *Id.*

Similarly, in *Akzo, N.V. v. United States International Trade Commission*, 808 F.2d 1471 (Fed. Cir. 1986), the Federal Circuit held that the applicant's argument in the USPTO distinguishing prior art was not a material misrepresentation because the prior art was before the examiner and he could reach his own conclusions regarding the art. *Id.* at 1482 ("The mere fact that [the applicant] attempted to distinguish the [claimed] process from the prior art does not constitute a material omission or misrepresentation. The examiner was free to reach his own conclusion regarding the [claimed] process based on the art in front of him."). *See also, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340,

1367 (Fed. Cir. 1998) (where the prior art in question was before the examiner, court found "no support for [defendant's] argument that [patentee] misrepresented the content of the PCT application, or that the examiner did not consider the PCT application adequately").[12]

The alleged "misrepresentations" at issue here do not even reach the level of conduct that courts have previously rejected as *insufficient* to support inequitable conduct. As a matter of law, Innogenetics' advocacy regarding the prior art – even as quoted selectively and out of context by Abbott – cannot amount to inequitable conduct.

B. Abbott's Efforts To Misuse Elements of The European Prosecution Should Be Rejected.

Abbott also attempts to make use of arguments advanced by Innogenetics in the European Patent Office during prosecution of the European counterpart to the Maertens PCT application to support its charge of inequitable conduct in the USPTO. Specifically, Abbott claims that the USPTO was misled because the prosecutor of the European patent

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[12] District courts have routinely followed this line of reasoning. *See, e.g., Miller Pipeline Corp. v. British Gas PLC*, 69 F. Supp. 2d 1129, 1136 n.4 (S.D. Ind. 1999) ("While we recognize that prospective patentees may mislead the patent examiner, it is important to remember that [the applicant] disclosed the [reference] and so the patent examiner had the opportunity to make its own determination, rather than relying exclusively on [the applicant's] representations."); *Becton Dickinson & Co. v. Syntron Bioresearch, Inc.*, 51 U.S.P.Q.2D (BNA) 1722, 1734 (S.D. Cal. 1998) ("The fact that [the applicants] attempted to distinguish the Campbell patent from the prior art does not constitute a material omission or misrepresentation. The examiners in this case were free to reach their own conclusions regarding the Campbell process and the [applicant's] demonstration based on the art in front of them." (internal quotation marks and citation omitted)); *Helver v. Novo Indus., Inc.*, 49 U.S.P.Q.2D (BNA) 1591, 1598 (S.D. Fla. 1998) ("The presentation of one interpretation of a patent by an applicant in order to distinguish it from his own does not constitute misrepresentation, as the intent of the applicant was to distinguish his patent from the prior art, not to mislead the examiner. The examiner was free to reach his own conclusion based on the art in front of him." (citation omitted)); *Liposome Co. v. Vestar, Inc.*, 36 U.S.P.Q.2D (BNA) 1295, 1316 (D. Del. 1994) ("While lawyers have a duty of candor to disclose material facts to an examiner, that duty does not stretch so far that it should inhibit a lawyer from making an argument to the examiner on how he or she should view those facts.").

application, Ms. Ann De Clercq, "extensively discussed (and amended [Innogenetics'] European claims in light of) the Cha [PCT application]" and "conceded" that the Cha PCT was the "'closest prior art.'" Abbott's Answer to Interrogatory No. 1, at 4 (Glazer Decl. Ex. 5).

Abbott's charges are without foundation as a matter of law. It is well understood that "theories and laws of patentability vary from country to country, as do examination practices." *Heidelberger Druckmaschinen Ag v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072 n.2 (Fed. Cir. 1994); *see also* Robert L. Harmon, *Patents and the Federal Circuit* § 1.4(d), at 32 (7th ed. 2005) ("due regard must be given to differences in foreign patent law"). The Federal Circuit has recognized that "the varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations inappropriate for consideration in a claim construction analysis of a United States counterpart." *TI Group Auto. Sys., Inc. v. VDO N. Am., L.L.C.,* 375 F.3d 1126, 1136 (Fed. Cir. 2004) (internal quotation marks omitted); *see also Molins*, 48 F.3d at 1180 (noting "the risk in relying on foreign patent prosecution in light of differences in disclosure requirements, claim practice, form of application, and standard of patentability"). Thus, "[c]aution is required when applying the action of a foreign patent examiner to deciding whether the requirements of 35 U.S.C. § 103 are met under United States law, for international uniformity in theory and practice has not been achieved." *Heidelberger*, 21 F.3d at 1072 n.2. For example, in *Medtronic, Inc. v. Daig Corp.*, 789 F.2d 903 (Fed. Cir. 1986), the court rejected as "specious" an argument that it adopt the conclusion of a German tribunal on the issue of obviousness,

holding that "[t]he patent laws of the United States are the laws governing a determination of obviousness/nonobviousness of a United States Patent in federal court." *Id.* at 907-08.

In other words, where a party seeks to make use of a foreign prosecution, in support of an inequitable conduct charge or otherwise, it has the duty to demonstrate identity, or at least, significant comparability, of procedures, practices, standards and context. Was a statement one of fact or of opinion? Was it made in relation to, or in the context of, the same claims? Were the applicable legal standard and procedures the same? Abbott has made, and can make, no such showing.

Such inquiries are not just advisable, they are a predicate to advancing such collateral evidence. As only one example, the scope of the claims was different in Innogenetics' European and U.S. proceedings. As explained by Mr. Sofocleous,

> As a first point, the arguments of Ms. De Clercq in Europe are addressed to claims that are not identical to the claims contained in the US application that issued as the Maertens, *et al.* '704 patent. For example, claim 1 of the European patent claims "[u]se of at least one probe . . .", a use claim which does not have a corresponding claim in the Maertens, *et al.* '704 patent. Further, claim 2 of the European patent recites a "[p]rocess of genotyping . . ." employing at least one probe "capable of hybridizing to a genotype specific target region . . . ." That claim language, however, is not present in the Maertens, *et al.* '704 patent. Rather, that phrase was specifically rejected by the US examiner in view of the Cha *et al.* 1991 publication and the Okamoto *et al.* US Patent No. 5,550,016. *See* the Final Office Action of April 18, 1997 at pages 3-4 (Bates 00783-00784). In response to that final rejection, Maertens *et al.* narrowed their claims to recite only methods of genotyping HCV in which probes specifically hybridize to the 5' UTR. Hence, the scope of the European claims is both different and broader than the scope of the US claims.

PPFF 89-93.

Moreover, the U.S. and European prosecutions were governed by different laws and different procedures. PPFF 98. For example, during prosecution the European counterpart to the '704 patent, Patent No. 0637342 (the "EP '342 application") Maertens *et al.* took advantage of a procedural mechanism called a "disclaimer" which is not available in the United States. PPFF 94. Importantly, the "disclaimer" related to claims that contained the phrase "capable of hybridizing" – which, as noted above, was a phrase that was eliminated from the U.S. claims by the U.S. examiner. PPFF 68, 95. Additionally, the EP '342 application was prosecuted under a "problem-solution" framework common in European practice in which a piece of art – regardless of whether it is relevant – is designated by either the examiner or the applicant as the "closest prior art" in order to facilitate the requisite problem-solution analysis. PPFF 96. This approach is not used in the United States. Ms. De Clercq explained the "closest prior art" framework was not a characterization of the art, but a framework set forth to pursue the prosecution. PPFF 96. In fact, Abbott's European patent law expert, Mr. Crease, agreed with Ms. De Clercq's description of "closest prior art." PPFF 97.

Regardless, where an application has been filed abroad on the same or a related subject matter as an application pending before the USPTO, the applicant's duty to disclose has been described as follows:

> Although international search reports may contain information material to patentability if they contain closer prior art than that which was before the United States examiner, it is the reference itself, not the information generated in prosecuting foreign counterparts, that is material to prosecution in the United States. The details of foreign prosecution are not an additional category of material information.

ATD Corp., 159 F.3d at 547. It is beyond dispute that the Cha PCT application was disclosed to both the U.S. and European examiners, and that both received the same search report listing the Cha PCT application as an "X" document. PPFF 99.

The Court can reject as a matter of law Abbott's efforts to bootstrap its inequitable conduct case by inappropriately attempting to import arguments made by Innogenetics in a collateral European proceeding.

C. This Court Can Find That The Cha PCT Application Was Expressly Considered On The Further Grounds That The Same Examiner Oversaw The Prosecution Of Both The '704 Patent And The U.S. Stage Of The Cha PCT Application.

Even if this Court were to draw all factual inferences in favor of Abbott, the evidence Abbott has proffered is insufficient as a matter of law to support a claim of inequitable conduct for all the reasons described above. This Court can grant Innogenetics' summary judgment motion on that basis alone. However, there is an additional reason why Abbott's inequitable conduct case must fail, resting as it does on the implied contention that the Cha PCT application was not fully considered during the examination of Innogenetics' '568 application. In making its charge of inequitable conduct relating to the Cha PCT application, Abbott either overlooked or willfully ignored the simultaneous prosecution of the U.S. counterpart of the Cha PCT application in the USPTO. Had Abbott performed even a minimal investigation into the prosecution and outcome of this concurrent U.S. application, it could not have contended in good faith that the Cha PCT application was not fully considered by the USPTO during the examination of Innogenetics' '568 (Maertens *et al.*) application.

Faced with Abbott's charges, Innogenetics did conduct such an investigation, as more fully explicated in the expert report of Michael Sofocleous (dkt. 43). As explained in that report, the supervisory patent examiner ("SPE")[13] overseeing the '704 patent prosecution, W. Gary Jones, was *simultaneously* overseeing the prosecution of U.S. patent application Serial No. 08/441,971 – the U.S. counterpart of the Cha PCT Application ("the Cha '971 application").[14] PPFF 109.

The Cha PCT application was the international filing of the Cha '971 application, and, as a result, *the Cha '971 application contained the same specification and claims as the Cha PCT application.* PPFF 105, 106. On December 12, 1995, the assistant examiner of the Cha '971 application issued an Office Action, which was signed by his supervisor, W. Gary Jones. PPFF 110. This indicates that, similar to the assistant examiner of the Maertens '568 application, the assistant examiner of the Cha '971 application was neither a primary examiner nor an examiner having signatory authority because the Office Action had to be reviewed by his supervisor, W. Gary Jones. PPFF 111.

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[13] Different assistant patent examiners handled the '704 patent application and the U.S. application based on the Cha PCT application. PPFF 35, 107. However, both of these examiners were supervised by supervisory patent examiner W. Gary Jones. PPFF 36, 108. As explained in the report of Michael Sofocleous, the assistant patent examiners had no signatory authority and examiner Jones was required to closely oversee each prosecution, and had the duty to declare an interference if the two applications claimed the same subject matter. PPFF 116.

[14] The '971 application was a continuation of U.S. application Serial No. 07/881,528, filed May 8, 1992, which in turn was a continuation-in-part of U.S. application Serial No. 07/697,326, filed May 8, 1991. PPFF 102. The Cha PCT Application claims priority to the '326 application. PPFF 103.

There is conclusive evidence that Mr. Jones, the SPE for both the Maertens '568 application and the Cha '971 application, was very familiar with the claims in each. Notably, Mr. Jones signed several office actions issued to Cha *et al.* during the time that the '704 patent was being prosecuted. PPFF 112-115. For example on April 18, 1997, Mr. Jones in his supervisory capacity signed the final office action sent to Maertens *et al.* for the '568 application. PPFF 112. Just six weeks later, on May 27, 1997, Mr. Jones signed in his supervisory capacity an office action sent to Cha *et al.* for the '971 application. PPFF 113.

As the supervisor in charge of the examination of both the Cha '971 application and the Maertens '568 application, it was the duty of SPE Jones to insure that an interference would be declared if the claims of these two applications were directed to the same subject matter. PPFF 116. But rather than initiating an interference, SPE Jones signed the Notice of Allowance for both the Maertens '568 application and the Cha '971 application which stated, respectively, as follows:

'568 Application to Maertens *et al.*	'971 Application to Cha *et al.*
The claims "are allowable over the prior art because the instant methods are concerned with 'genotyping' HCV rather than just 'detecting' HCV."	The claims "are allowable over the prior art because these authors are the first to teach or reasonably suggest the non-HCV-1 hepatitis C virus nucleic acids… utilized in the claimed invention ***to detect*** hepatitis C virus nucleic acids."

PPFF 117 (emphasis added). Notably, Mr. Jones allowed Cha *et al.'s* claims to a "method of *detecting* one or more genotypes of hepatitis C virus" comprising the steps of

hybridizing nucleotide probes including probes in the 5'UTR of HCV nucleic acids. PPFF 118 (emphasis added).

On this record, where the Cha PCT application was explicitly disclosed, not once but twice, to the USPTO by Innogenetics, and where the supervising examiner of the Maertens '568 application not only possessed *actual* knowledge of the U.S. counterpart of the Cha PCT application, but contemporaneously granted patently distinct claims for each application and did *not* declare an interference, Abbott's assertions of inequitable conduct with respect to the Cha PCT application are frivolous.

CONCLUSION

In a recent dissent, Circuit Judge Newman commented on the history of inequitable conduct in the Federal Circuit:

> "As is known, about 20 years ago inequitable conduct was frequently pleaded as a defense to patent infringement; a patent that is 'unenforceable' due to a finding of inequitable conduct is dead. The defense was so misused by alleged infringers that the Federal Circuit once called this defense a 'scourge' on US patent litigation . . . . The famous *Kingsdown* [decision] seemed to put a stop to the defense of inequitable conduct. . . ."
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> * * *
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> In *Kingsdown*, the Federal Circuit held that in order to invalidate a patent for inequitable conduct in obtaining the patent, there must be both a material misrepresentation and intent to deceive. The court established that it is necessary to consider all of the evidence including evidence of good faith, and that both materiality and deceptive intent must be proved by clear and convincing evidence. *Kingsdown* established that no longer would negligence alone support a holding of inequitable conduct. The Federal Circuit did not believe that inventors and patent attorneys are more or less virtuous than anyone else; they simply held that charges of deceptive action must be proved on objective standards, as the law requires for property-

> forfeiting charges under the common law. Experience shows that *Kingsdown's* simple changes in the law were an important contribution to restoration of the patent system as an incentive to industrial innovation, for this court has recognized that a "patentee's oversights are easily magnified out of proportion by one accused of infringement."

Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1195, 1196 (Fed. Cir. 2006) (citations omitted).

Charges of fraud on the USPTO cannot be dealt with lightly – either by the patent holder, or by the Court. The patent holder risks not only its lawsuit (including being charged with its opponent's legal fees), but its invention too: the court is forced to invest scarce resources in order to deal properly with such charges. And the patent system as a whole suffers when such charges are carelessly plead and casually pursued. Here Abbott has made half-baked charges of inequitable conduct followed by half-hearted attempts to defend them. It demonstrably failed to make the kind of investigation that should be required before making this serious charge. It has not made, and cannot make, any showing that its accusations amount to the making of false statements, much less ones made in bad faith and with intent to deceive the USPTO. This Court should grant Innogenetics' Motion for Summary Judgment of No Inequitable Conduct.

Dated this 15th day of May, 2006.

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